

REMARKS

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Entry of the amendments is proper under 37 CFR §1.116, because the amendments place the application in condition for allowance and do not raise any new issue requiring further search and/or consideration. The amendments are necessary and were not earlier presented, because they are made in response to arguments raised in the final rejection. Entry of the amendments is thus respectfully requested.

Claims 12, 14, 22 and 28-33 are pending in this application.

Claims 28 and 31 have been amended to recite a composition comprising the copolymer of claim 12 or 14 “and a solvent”. Support for these amendments can be found on page 16, lines 6-13 of the marked-up version of the substitute specification.

I. Claim Rejection Under 35 U.S.C. § 112

The Examiner rejects claims 28 and 31 under 35 U.S.C. 112, second paragraph, as being indefinite. Claims 28 and 31 have been amended to recite a composition comprising the copolymer of claim 12 or 14 “and a solvent”, rendering the rejection moot. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

II. Claim Rejections Under 35 U.S.C. § 102

The Examiner rejects claims 12, 30 and 31 under 35 U.S.C. § 102(b) as being anticipated by Hoshi et al. (WO 02/17848; US 2003/0166763); and rejects claims 14, 22 and 28 under 35 U.S.C. 102(b) as being anticipated by Hoshi et al. As applied to the amended claims, Applicants respectfully traverse the rejections.

Claims 12 and 14 each recite “A copolymer **consisting of a partially hydrolyzed polyvinyl alcohol** having an average polymerization degree of 300 to 500 and **a polymerizable vinyl monomer** in a weight ratio of 6:4 to 9:1, wherein: **the polymerizable vinyl monomer consists of acrylic acid and methyl methacrylate** combined in a weight ratio of 3:7 to 0.5:9.5 in the copolymer”. Accordingly, the polymerizable vinyl monomer in the copolymer of claims 12 and 14 consists of “acrylic acid and methyl methacrylate”.

As the Examiner indicates on page 3, lines 17-19 of the Office Action, Hoshi et al. describe, in Synthesis Example 1, a copolymer consisting of PVA-SH, methacrylic acid (MAA) and methyl methacrylate (MMA). The reference does not disclose a copolymer wherein the polymerizable vinyl monomer consists of “**acrylic acid** and methyl methacrylate”, as recited in claims 12 and 14.

The Examiner takes the position that “It is easily envisaged to substitute the methacrylic acid with acrylic acid as those are the more preferred monomers [0033]” (see Office Action, page 3, lines 19-21). Applicants respectfully disagree.

One of ordinary skill in the art could not simply substitute acrylic acid for methacrylic acid, because the viscosity of the resulting copolymer would increase and the water solubility would decrease, as shown in the Additional Test results below. Therefore, substituting methacrylic acid for acrylic acid would result in a copolymer having completely different properties and structural features.

Additional Test

The following table shows the differences of physical properties between two copolymers (the Present Invention and the Control) consisting of:

[Present Invention]: ① PVA (mixture ratio = 1 (polymerization degree: 500) : 9 (polymerization degree: 1500)), ② acrylic acid and ③ MMA.

[Control]: ①, ④ MAA and ③.

Table

	Present invention	Control
①PVA/②acrylic acid	75/25	-
①PVA/④MAA	-	75/25
polymerization degree of PVA:500	10/90	10/90
polymerization degree of PVA:1500		
③MMA/②acrylic acid	70/30	-
③MMA/④MAA	-	70/30
Viscosity mPa · s/25℃	20100	91600
Water solubility	within 10 min.	over 10 min.

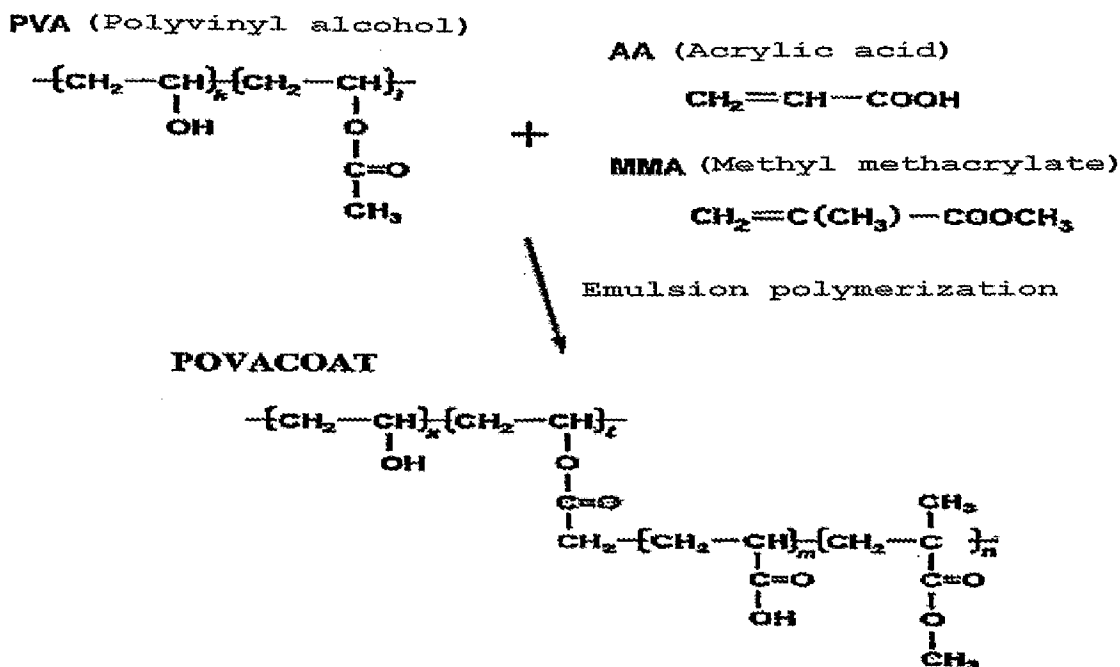
As shown in the Table, the viscosity of the control copolymer, which consists of PVA, **MAA (methacrylic acid)** and MMA (methyl methacrylate), is much higher than that of the copolymer of claims 12 and 14, which consists of PVA, **acrylic acid** and MMA. Furthermore, as shown in the Table, the water solubility of the control copolymer is much lower than that of the copolymer of claims 12 and 14. As a result, it would be difficult to handle the control copolymer as a coating agent, and the resulting control copolymer would not be suitable as an aqueous coating agent. Therefore, the resulting control copolymer is completely different in physical properties and structural features from the copolymer of claims 12 and 14.

In addition, the partially hydrolyzed polyvinyl alcohol (PVA) in the copolymer of claims 12 and 14 is different from the PVA used in the synthetic examples of Hoshi et al. cited by the Examiner.

The PVA used in Synthesis Example 1 of Hoshi et al. is actually PVA-SH, which is a polyvinyl alcohol having **a terminal thiol group** (i.e., a polyvinyl alcohol modified with SH). On the other hand, claims 12 and 14 recite a copolymer **consisting of** “a partially hydrolyzed polyvinyl alcohol”.

Furthermore, the bond-structure of a copolymer obtained from a polyvinyl alcohol having a terminal thiol group (PVA-SH), MAA and MMA is completely different from a copolymer obtained from a partially hydrolyzed polyvinyl alcohol, MAA and MMA.

As is clear from the enclosed References 1 and 2, in particular Reference 2, a copolymer obtained from a partially hydrolyzed polyvinyl alcohol, MAA and MMA is a graft copolymer in which an acetyl moiety is bonded, as depicted below from Reference 2.



On the other hand, a copolymer obtained from **polyvinyl alcohol having a terminal thiol group (PVA-SH)**, **MAA** and **MMA** is a linear (straight) copolymer in which the SH moiety is linearly bonded (i.e., bonded in a straight chain).

One of ordinary skill in the art would clearly recognize that a graft copolymer has low viscosity and strong adhesive properties to a coated layer, as compared with a linear (straight) copolymer.

Accordingly, the copolymer of claims 12 and 14 “consisting of a **partially hydrolyzed polyvinyl alcohol** having an average polymerization degree of 300 to 500 and a **polymerizable vinyl monomer** in a weight ratio of 6:4 to 9:1, wherein: **the polymerizable vinyl monomer consists of acrylic acid** and methyl methacrylate combined in a weight ratio of 3:7 to 0.5:9.5 in the copolymer” is completely different from the copolymer disclosed in Hoshi et al.

Therefore, Hoshi et al. fail to disclose the copolymer of claims 12 and 14, and thus claims 12 and 14 are not anticipated by the reference.

Claims 22, 28, 30 and 31 depend from claim 12 or 14, and thus also are not anticipated by the reference.

Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

III. Claim Rejections Under 35 U.S.C. § 103

The Examiner rejects claim 29 under 35 U.S.C. 103(a) as being unpatentable over Kurihara et al. (US 4,341,563) in view of Hoshi et al.; rejects claim 32 under 35 U.S.C. 103(a) as being unpatentable over Kurihara et al. in view of Hoshi et al.; and rejects claim 33 under 35 U.S.C. 103(a) as being unpatentable over Zeidler et al. (US 6,001,391) in view of Hoshi et al. Applicants respectfully traverse the rejections.

Kurihara et al. and Hoshi et al.

As the Examiner indicates, Kurihara et al. describe a coating solution used to form a film comprising a water-soluble film base, such as polyvinyl alcohol, and a coated solid medicine (see Office Action, page 5, lines 15-17). The Examiner acknowledges that the reference does not disclose the copolymer of claims 12 and 14, but asserts that Hoshi et al. remedy this deficiency (see Office Action, page 5, lines 18-22 and page 6, lines 5-9).

However, as discussed above, the structural properties of the PVA-SH copolymer disclosed in Hoshi et al. are quite different from the copolymer of claims 12 and 14. In addition, polyvinyl alcohol is structurally different from a copolymer of a partially hydrolyzed polyvinyl alcohol, MAA and MMA.

Accordingly, Kurihara et al. and Hoshi et al. fail to disclose or suggest the copolymer of claims 12 and 14.

Claims 29 and 32 depend indirectly from claim 12 or 14. Therefore, claims 29 and 32 would not have been obvious over the references.

Zeidler et al. and Hoshi et al.

As the Examiner indicates, Zeidler et al. describe that polyvinyl alcohol or copolymers of MMA and acrylic acid are used as a binder (see Office Action, page 7, lines 9-11). The Examiner acknowledges that the reference does not disclose the copolymer of claims 12 and 14, but asserts that Hoshi et al. remedy this deficiency (see Office Action, page 7, line 12 – page 8, line 5).

However, as discussed above, the structural properties of the PVA-SH copolymer disclosed in Hoshi et al. are quite different from the copolymer of claims 12 and 14. Moreover, polyvinyl alcohol or copolymers of MMA and acrylic acid are structurally different from the copolymer of claims 12 and 14. Accordingly, Zeidler et al. and Hoshi et al. fail to disclose or suggest the copolymer of claims 12 and 14.

Claims 29, 32 and 33 depend indirectly from claim 12 or 14. Therefore, claims 29, 32 and 33 would not have been obvious over the references.

Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

IV. **Conclusion**

For these reasons, Applicants take the position that the presently claimed invention is clearly patentable over the applied references.

Therefore, in view of the foregoing amendments and remarks, it is submitted that the rejections set forth by the Examiner have been overcome, and that the application is in condition for allowance. Such allowance is solicited.

Respectfully submitted,

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Attachments: Reference 1: Introduction of Polymer Drug, and its English translation
Reference 2: JP Master File of POVACOATTM and its English translation